EXHIBIT A

CFSAN/Office of Cosmetics and Colors
January 24, 2006; Revised April 20, 2007

Color Additives and Cosmetics

Color additives are subject to a strict system of approval under U.S. law [FD&C Act, sec. 721; 21 U.S.C. 379e]. Except in the case of coal-tar hair dyes, failure to meet U.S. color additive requirements causes a cosmetic to be adulterated [FD&C Act, sec. 601(e); 21 U.S. Code 361(e)]. Color additive violations are a common reason for detaining imported cosmetic products offered for entry into this country.

More information on
- Color Additives
- Color Additives and Cosmetics

Some Basic Requirements

If your product (except coal-tar hair dyes) contains a color additive, by law [FD&C Act, Sec. 721; 21 U.S.C. 379e; 21 CFR Parts 70 and 80] you must adhere to requirements for:

- **Approval.** All color additives used in cosmetics (or any other FDA-regulated product) must be approved by FDA. There must be a regulation specifically addressing a substance's use as a color additive, specifications, and restrictions.
- **Certification.** In addition to approval, a number of color additives must be batch certified by FDA if they are to be used in cosmetics (or any other FDA-regulated product) marketed in the U.S.
- **Identity and specifications.** All color additives must meet the requirements for identity and specifications stated in the Code of Federal Regulations (CFR).
- **Use and restrictions.** Color additives may be used only for the intended uses stated in the regulations that pertain to them. The regulations also specify other restrictions for certain colors, such as the maximum permissible concentration in the finished product.

How are color additives categorized?

The FD&C Act Section 721(c) [21 U.S. C. 379e(c)] and color additive regulations [21 CFR Parts 70 and 80] separate approved color additives into two main categories: those subject to certification (sometimes called "certifiable") and those exempt from certification. In addition, the regulations refer to other classifications, such as straight colors and lakes.

- **Colors subject to certification.** These color additives are derived primarily from petroleum and are sometimes known as "coal-tar dyes" or "synthetic-organic" colors. (**NOTE:** Coal-tar colors are materials consisting of one or more substances that either are made from coal-tar or can be derived from intermediates of the same identity as coal-tar intermediates. They may also include diluents or substrata. (See *Federal Register*, May 9, 1939, page 1922.)

Today, most are made from petroleum.)
  - Except in the case of coal-tar hair dyes, these colors must not be used unless FDA has certified that the batch in question has passed analysis of its composition and purity in FDA's own labs. If the batch is not FDA-certified, don't use it.
  - These certified colors generally have three-part names. The names include a prefix FD&C, D&C, or External D&C; a color; and a number. An example is "FD&C Yellow No. 5." Certified colors also may be identified in cosmetic ingredient declarations by color and number alone, without a prefix (such as "Yellow 5").
- **Colors exempt from certification.** These color additives are obtained primarily from mineral, plant, or animal sources. They are not subject to batch certification requirements. However, they still are considered artificial colors, and when used in cosmetics or other FDA-regulated products, they must comply with the identity, specifications, uses, restrictions, and labeling requirements stated in the regulations [21 CFR 73].
- **Straight color.** "Straight color" refers to any color additive listed in 21 CFR 73, 74, and 81 [21 CFR 70.3(j)].
- **Lake.** A lake is a straight color extended on a substratum by adsorption, coprecipitation, or chemical combination that does not include any combination of ingredients made by a simple mixing process [21 CFR 70.3(l)]. Because lakes are not soluble in water, they often are used when it is important to keep a color from "bleeding," as in lipstick. In some cases, special restrictions apply to their use. As with any color additive, it is important to check the Summary of Color Additives and the regulations themselves [21 CFR 82, Subparts B and C] to be sure you are using lakes only for their approved uses.

How can I guard against color additive violations?

Several precautions can help you avoid color additive violations that will cause your cosmetic to be adulterated:

- **Do not confuse certified colors with their uncertified counterparts.** For example, FD&C Yellow No. 5 is the certified form of tartrazine, and is approved for use in cosmetics generally. But tartrazine, which has not undergone FDA analysis and received FDA certification, must not be substituted for or identified in an ingredient declaration as FD&C Yellow No. 5.
- **Do not confuse certified colors with colors identified only by a Colour Index (CI) number, or by the E number sometimes used in European color identification.** You must not use a color subject to certification unless FDA has certified the batch in question [FD&C Act, sec. 721(a)(1)(A). A CI or E number does not indicate FDA certification.
- **When purchasing color additives subject to certification, check the label.** If the lot is certified, the color's label must state the legal name for the color (such as "FD&C Yellow No. 5"), or, if it is a mixture, the name of each ingredient; the FDA lot certification number; and the color's uses and restrictions as stated in the CFR [21 CFR 70.25).
- **Check the Summary of Color Additives on FDA's Web site.** Although this table is not a substitute for the regulations, it is an easy-to-use reference that introduces you to FDA-approved color additives and directs you to the regulations addressing specific color additives.
- **Become familiar with the regulations themselves.** The color additive regulations are in 21 CFR Parts 70 through 82. Specific color additives are addressed in Parts 73, 74, and 82. The

color additive regulations are posted on FDA's Web site at http://www.cfsan.fda.gov/~dms/col-cfr.html. To purchase printed copies of the CFR by credit card, call the Government Printing Office at (202) 512-1800, Monday through Friday, from 8:00 a.m. to 4:00 p.m., Eastern Standard Time. To pay by check, write to the Superintendent of Documents, Attn: New Orders, P.O. Box 371954, Pittsburgh, PA 15250-7954. Contact the Government Printing Office directly for current costs.

- **Confirm the status of color additives before use.** There may be changes in color additive approvals and changes in the uses and restrictions that apply to a color additive. Such changes may affect colors subject to certification as well as colors exempt from certification. To stay current with the regulations, you can check the latest edition of the CFR and FDA Dockets. You also may contact FDA at Color.Cert@fda.hhs.gov.
- **When purchasing colors subject to certification, confirm that the manufacturer has requested certification.** For example, you can choose a manufacturer from FDA's list of companies that have requested color certification within the past two years. This list is posted on FDA's Web site at http://www.cfsan.fda.gov/~dms/col-comp.html and is available as Document #710 by mail or fax through the Center for Food Safety and Applied Nutrition Outreach and Information Center's toll-free phone number, 1-888-SAFEFOOD. If the company that appears on the color additive label is not on this list, you may contact FDA at Color.Cert@fda.hhs.gov to determine whether the company has in fact requested certification of its color additives.

Must I match colors with intended use?

Yes. No matter whether a particular color is subject to certification or exempt from certification, U.S. law prohibits its use in cosmetics (or any other FDA-regulated product) unless it is approved specifically for the intended use [FD&C Act, sec. 721(a)(1)(A); 21 U.S.C. 379e(a)(1)(A)].

The regulations also restrict intended use as follows:

- **Eye-area use:** You may not use a color additive in the area of the eye unless the regulation for that additive specifically permits such use [21 CFR 70.5(a)]. The "area of the eye" includes "the area enclosed within the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, and conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge" [21 CFR 70.3(s)]. Although there are color additives approved for use in products such as mascara and eyebrow pencils, none is approved for dyeing the eyebrows or eyelashes.
- **Externally applied cosmetics:** This term does not apply to the lips or any body surface covered by mucous membrane. For instance, if a color additive is approved for use in externally applied cosmetics, you may not use it in products such as lipsticks unless the regulation specifically permits this use [21 CFR 70.3 (v)].
- **Injection:** No color additive may be used in injections unless its listing in the regulations specifically provides for such use. This includes injection into the skin for tattooing or permanent makeup. The fact that a color additive is listed for any other use does not mean that it may be used for injections [21 CFR 70.5(b)]. There are no color additives listed in the regulations as approved for injections.

What about special effects and novelty use?

No matter how exotic or novel the color additive or its intended use, it is subject to the same regulations as the more everyday colors and products. The following items are a sampling of some out-of-the-ordinary color additives. This list is not exhaustive. Rather, it is intended to show how the regulations apply to such colors:

- **Color-changing pigments:** Colors that change in response to such factors as change in pH or exposure to oxygen or temperature are subject to the same regulations as all other color additives.
- **Composite pigments:** Color additives used in combination to achieve variable effects, such as those found in pearlescent products, are subject to the same regulations as all other color additives. Some color additives, when used in combination, may form new pigments, which may not be approved for the intended use. An example is a "holographic" glitter, consisting of aluminum an approved color additive bonded to an etched plastic film.
- **Fluorescent colors:** Only the following fluorescent colors are approved for use in cosmetics, and there are limits on their intended uses: D&C Orange No. 5, No. 10, and No. 11; and D&C Red No. 21, No. 22, No. 27, and No. 28 [21 CFR 74.2254, 74.2260, 74.2261, 74.2321, 74.2322, 74.2327, and 74.2328].
- **Glow-in-the-dark colors:** Luminescent zinc sulfide is the only approved glow-in-the-dark color additive [21 CFR 73.2995].
- **Halloween makeup:** These products are considered cosmetics [FD&C Act, sec. 201(i); 21 U.S.C. 321(i)] and are therefore subject to the same regulations as other cosmetics, including the same restrictions on color additives.
- **Liquid crystal colors:** These additives, which produce color motifs in a product through diffraction, are unapproved color additives. Their use in cosmetics is therefore illegal [FD&C Act, sec. 601(e); 21 U.S.C. 361(e)].
- **Tattoo pigments:** As noted above, no color additives are approved for injection into the skin, as in tattoos and permanent makeup.
- **Theatrical makeup:** Like Halloween makeup, these products are considered cosmetics [FD&C Act, sec. 201(i); 21 U.S.C. 321(i)] and are therefore subject to the same regulations as other cosmetics, including the same restrictions on color additives.

EXHIBIT B

CFSAN/Office of Cosmetics and Colors
December 27, 2007

Lipstick and Lead: Questions and Answers

The Food and Drug Administration (FDA) has received a number of inquiries regarding reports of levels of lead in lipstick. The following information is drawn from responses to those inquiries.

What is FDA's legal authority over cosmetics?

FDA regulates cosmetics under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The Act does not subject cosmetics to pre-market approval by FDA, with the exception of most color additives. It does, however, require that cosmetics marketed in interstate commerce be safe when used as directed in the labeling or under customary conditions of use. The FD&C Act subjects all color additives (other than coal-tar hair dyes) used in FDA-regulated products, including those used in lipstick, to pre-market approval. The listing regulation for each approved color additive includes limits for trace levels of heavy metal contaminants, if appropriate. FDA can and does take action against firms and individuals who violate the law, as determined by public health priorities and resources. To learn more on this subject, please refer to FDA Authority Over Cosmetics.

Has FDA been aware of concerns about lead in lipstick?

Reports about lead in lipstick are not new. In the 1990s, reports of analytical results from a commercial testing laboratory suggested that traces of lead in lipstick might be of concern. Subsequent evaluation by FDA of that laboratory's test results determined that an unvalidated and inappropriate testing method had been used. FDA's analyses did not detect levels of lead that would be considered harmful. The levels found did not exceed trace amounts that would be unavoidable even under conditions of good manufacturing practice, given background

levels in the environment.

Has FDA published tolerance levels for lead in lipstick?

FDA has not published tolerance levels for contaminants, such as lead, in cosmetics. However, FDA does set specifications for impurities, such as lead, for color additives used in cosmetics. In addition, as noted above, cosmetics must by law be safe when used as directed in the labeling or under customary conditions of use.

It's been reported that levels of lead in certain lipstick exceed those for candy. Is this a fair comparison?

FDA has yet to confirm the latest reports. However, it is not valid to compare the FDA-recommended level for lead in candy, a product intended for ingestion and which may be consumed on a regular basis, with lead levels in lipstick, a product intended for topical use and which is ingested in much smaller quantities than candy.

Is FDA following up on the latest reports?

Because allegations regarding lead in lipstick surface periodically, and because of the amount of time since FDA last surveyed lipsticks in the marketplace, FDA has decided to allocate the resources necessary to conduct independent testing of a selection of lipstick on the market. FDA has obtained commercial samples of the same lipstick brands cited in the recent report. FDA laboratories have been adapting a previously validated, state-of-the-art method to do the analyses.

Does FDA intend to take enforcement action, given the latest report?

As a science-based public health agency, FDA bases its actions upon authoritative scientific evidence and the agency's authority under the law. FDA takes seriously its commitment to develop and implement policies that will promote consumer safety and enhance public health. If FDA determines that a health hazard exists, the agency will advise the industry and the public, and will consider its options under the authority of the FD&C Act in protecting the health and welfare of consumers.

Cosmetics

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FDA/Center for Food Safety & Applied Nutrition
Hypertext updated by bxm/shm December 27, 2007

EXHIBIT C

November 2006

Guidance for Industry

Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy

Additional copies are available from:
Office of Plant and Dairy Foods, HFS-300
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 301-436-2022
http://www.cfsan.fda.gov/guidance.html

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
November 2006

Guidance for Industry [1]

Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy

This guidance document represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for

implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. Introduction

This guidance provides a recommended maximum lead level of 0.1 ppm in candy[2] likely to be consumed frequently by small children. FDA considers the recommended maximum lead level to be achievable with the use of good manufacturing practices in the production of candy and candy ingredients and to be protective of human health. For additional discussion of the background and rationale underlying this recommended level, see "Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children."

In addition to announcing the recommended maximum lead level, FDA as explained below, is rescinding the previous 0.5 ppm guideline for considering enforcement action against candy products likely to be consumed frequently by small children. FDA is prepared to take enforcement action against any candy product containing lead at levels that may pose a health risk. Further, FDA is reiterating its enforcement policy toward the use of lead-based ink on candy wrappers as originally stated in its 1995 letter to the industry on this subject.

FDA considers the issuance of this guidance to be a prudent public health measure consistent with the Agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can be practicably obtained.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Discussion

A. Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children

FDA is recommending that lead levels in candy products likely to be consumed frequently by small children not exceed 0.1 ppm because such levels are achievable under good manufacturing practices and would not pose a significant risk to small children for adverse effects. This recommended maximum level of 0.1 ppm for lead in candy likely to be consumed frequently by small children is consistent with the FDA's longstanding goal of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can be practicably obtained. This recommendation is further discussed in the supporting document for this guidance noted above.

B. Enforcement Policy for Lead in Candy Likely To Be Consumed Frequently by Small Children

Because it is no longer regarded as consistent with the agency's policy of reducing lead levels in

the food supply to reduce consumers' lead exposure to the lowest level that can practically be obtained FDA is rescinding the guidance it provided in the 1995 letter that stated that, where frequent consumption of candy products by small children could be anticipated, FDA would consider taking regulatory action against candy with lead levels that exceed 0.5 ppm.

FDA is now prepared to take enforcement action against any candy product containing lead at levels that may pose a health risk. FDA intends to consider several factors in bringing enforcement actions regarding lead in candy, including the level of lead present, the best available consumption data, and the lead exposure that would result from consumption of the product.

C. Enforcement Policy for Use of Lead-Based Inks on Candy Wrappers

FDA is reiterating in this guidance that FDA's policy toward the use of lead-based ink on candy wrappers remains as stated in its 1995 letter to the industry on this subject:

> Generally speaking, if lead derived from a lead-based printing ink is found on the portion of the package that directly contacts food or, if such lead could be expected to migrate into the packaged food, the product would likely be regarded as being in violation of the Federal Food, Drug, and Cosmetic Act. Use of the printing ink only on the outer (non-food contact) surface of the package does not ensure that it will not contaminate the food.

Suitable non-lead-based printing inks[3] are widely available for use in food packaging, and we continue to strongly urge all candy manufacturers, including those whose products are offered for import into this country, to refrain from the use of lead-based printing inks on their packaging materials.

In addition, the use of lead-based printing inks on candy wrappers may subject a firm to regulatory action by the U.S. Consumer Product Safety Commission under the Federal Hazardous Substances Act (see Letter to US candy importers - July 9, 2004 (PDF) and Letter to candy producers in Mexico (English version) - July 12, 2004 (PDF) for additional information). Furthermore, the use of lead or lead-based inks in or on packaging, including candy wrappers, is subject to state Toxics in Packaging legislation which has been enacted in nineteen U.S. states, (see Toxics in Packaging Clearinghouse Fact Sheet (PDF) for additional information).

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[1] This guidance has been prepared by the Office of Plant and Dairy Foods in the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

[2] We have included within the broad category of candy, "Mexican-style" candy. "Mexican style" refers to candy which contains ingredients popular in Mexico, such as chili and tamarind, which are not typically found in domestic candy in the U.S. Within the category of "Mexican-style" candy, we have included powdered snack mix products, which are generally made in Mexico and typically contain combinations of salt, chili powder, sugar and flavoring. These products, popular with children and adults, may be sold alongside of candy in retail outlets, and can be consumed directly from the container like candy, as well as being sprinkled onto fruits and vegetables or in

beverages.

[3] Non-lead based printing inks may contain incidental lead at trace levels, e.g., < 0.001%, but, do not contain intentionally added lead as would for example lead chromate inks, which can contain > 2% lead.

Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children October 2006

Guidance for Industry: Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy Wrappers June 13, 1995

Consumer Product Safety Commission: Letter to U.S. Candy Importers (available in PDF) July 9, 2004

Consumer Product Safety Commission: Letter to Candy Producers in Mexico (available in PDF) July 12, 2004

Toxics in Packaging Clearinghouse Fact Sheet (available in PDF) January 2005

This document supercedes "Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy," December 2005

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FDA/Center for Food Safety & Applied Nutrition
Hypertext updated by dav November 24, 2006

EXHIBIT D

EX. D

LEAD EXPOSURE COMPARISON (LIPSTICK & CANDY)

These calculations are based on (and assume the truth of) the following complaint allegations:

1. A typical woman inadvertently ingests 4 lbs. of lipstick in her lifetime (Cmplt. ¶ 23).
2. The majority of women are wearing lipstick by 10 years of age (Cmplt., ¶ 24),
3. The FDA has established a 0.1 ppm limit for lead in candy (Cmplt. ¶ 28),
4. Lipsticks, like candy, are ingested into the body (Cmplt. ¶ 29); and
5. The Dior Addict lipstick at issue in this lawsuit contains 0.21 ppm of lead (Cmplt. ¶ 30).

The calculation is also based on common sense, irrefutable assumptions of which this Court may properly take judicial notice.

1. The life-span of a typical woman in the United States is 70 years.[1] (Based on plaintiff's allegation that the majority of women begin wearing lipstick by age 10, the relevant time period then is 60 years.)
2. The weight of a single serving of candy (the serving size underpinning the FDA's guidance regarding lead in candy) is 21 grams.[2]
3. Math conversions:

   1 lb = 453.49237 grams (g)

   .0000001 gram = 1 microgram (μg)

   1 μg/g = 1 ppm

Calculation #1: Lifetime Exposure to Lead from Lipstick

4 lbs of lipstick = 4 lbs x 453.49237 g/lb = 1813.96948 g of lipstick in lifetime

1813.96948 grams of lipstick ingested over 60 years (70 -10)

0.21 ppm of lead (Pb) = 0.21 μg/g

Total Pb from lipstick in lifetime = 1813.96948 g x 0.21 μg/g = 380.9335908 μg of Pb

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[1] The U.S. Census Bureau actually reports that the average life expectancy for a woman in the United States as of 2000 to be 79 years, a fact of which this Court may properly take judicial notice. For purposes of the above calculation, LVMH uses the more conservative lifespan of only 70 years.

[2] *See* FDA Import Alert #33-10, "Detention Without Physical Examination of Candy Due to Lead" (orig. June 2005, rev. March 2008) (noting that the FDA's lead-in-candy Guidance Statement was based upon an estimated daily candy consumption of 21 grams), at http://www.fda.gov/ora/fiars/ora_import_ia3310.html. A copy of Import Alert #33-10, of which the Court may properly take judicial notice, is attached as Ex. E.

EX. D

Thus, based on 4 lbs. total lipstick ingestion, the typical woman ingests 380.9335908 μg of lead from lipstick in her lifetime.

Calculation #2: Lifetime Exposure to Lead from Candy

The FDA standard is based on 21 grams daily serving of lead-containing candy.

Total candy ingested over lifetime = 21 grams x 365 days x 60 years = 459,900 grams

(1,014.12952 lbs of candy over lifetime or approximately 16.9 lbs/year over 60 years)

0.1 ppm of lead (Pb) = 0.1 μg/g

Total Pb from candy in lifetime = 45,990 μg of Pb

Thus, the typical woman ingests 45,990 μg of of Pb from candy in her lifetime.

Calculation #3: Comparative Lead Exposure Calculation by Percentage

380.9335908 / 45,990 = n/100

n = 0.828296566

Conclusion: Daily lead exposure from lipstick is less than 1% (0.828296566) of the daily lead exposure standard the FDA determined to be safe for candy intended for ingestion by children. In other words, the total lead exposure from a serving of candy is 100 times greater than the lead exposure from total daily lipstick ingested by a typical woman.

LEAD EXPOSURE COMPARISON (LIPSTICK TO PPTIL):

The FDA-determined Provisional Tolerable Intake Level ("PPTIL") for lead is 75 μg/day for adults, 15 μg/day for children 7 years of age and up, and 6 μg/day for children 6 years of age and below.[3] Applying the lead-exposure levels determined above,

Daily lead exposures from lipstick = 380.9335908 μg/day ÷ 21,900 days [365 days x 60 years] = 0.017394228 μg/day

Conclusion: The level of lead exposure from lipstick is 0.017394228 μg/day, which is 0.023192305% of the FDA-determined PPTIL of 75 μg/day for lead for adults. By comparison, the level of lead exposure from candy is 2.8% of PPTIL for adults, more than 100 times greater than lipstick.

[3] *See* Health Consultation Exposure Investigation ("HHS Report"), U.S. Dep't of Health & Human Svcs., June 9, 2005 (identifying PTTIL for lead in children and adults). A hardcopy of the excerpted HHS Report, of which this Court may properly take judicial notice, is attached as Ex. F to the accompanying memorandum.

EXHIBIT E

IA #33-10, REVISED 6/22/05 - IMPORT ALERT, #33-10, "DETENTION WITHOUT PHYSICAL EXAMINATION OF CANDY DUE TO LEAD"
ATTACHMENT, REVISED - 3/10/08

NOTE: This import alert is being reissued to accommodate additional candy products subject to detention without physical examination. Asterisks bracket changes (***).

TYPE OF ALERT: Detention Without Physical Examination (DWPE)

NOTE: This import alert contains guidance to FDA field personnel only. It does not establish any requirements, or create any rights for, or obligations on, FDA or regulated entities.

PRODUCT : *** See Attachment ***

PRODUCT CODE: See attachment

PROBLEM: Excessive levels of lead (HMPB)

PAC FOR COLLECTION : 04019A

COUNTRY : See attachment

MANUFACTURER/ SHIPPER : See attachment

MANUFACTURER/ SHIPPER I.D.#: See attachment

CHARGE : The article is subject to refusal of admission pursuant to Section 801(a)(3), in that the article appears to bear or contain a poisonous or deleterious substance, lead which may render it injurious to health [Adulteration, Section 402(a)(1)];

and

Its container (paper wrapper) is composed in part of a poisonous or deleterious substance, lead, which may render the contents injurious to health [Adulteration,Section 402(a)(6)];

and/or

It appears to bear or contain a food additive, lead, that is unsafe within the meaning of Section 409 [Adulteration 402(a)(2)(C)]."

RECOMMENDING OFFICE: LOS-DO (HFR-PA256)
SAN-DO (HFR-PA152)

REASON FOR ALERT: From August through October 1994, lollipops from Mexico were detained because of high lead levels. Lead was also found in some of the wrappers. In 1995, FDA initially provided guidance in this import alert that it would consider action against candy products that exceeded 0.5 ppm lead. This guidance allowed for a lead intake from these candies of no more than approximately 10 micrograms of lead per day, based upon an estimated daily candy consumption of 21 grams. More recently, FDA has learned that some candy products have serving sizes substantially larger than 21 grams and FDA believes that children are likely to consume the entire product on one eating occasion. In order to continue to provide the comparable level of protection to children when they eat these larger products, i.e., no more than approximately 10 micrograms per serving, FDA has revised the import alert to indicate that it may also consider action against candy products containing 0.5 ppm or less lead, when the amount of lead per serving is 10 micrograms or more.

In January 1995, SAN-DO analyzed a sample of tamarind candy packaged in green ceramic containers and found approximately 25 parts per million lead.

In July 1996, FDA learned of an investigation conducted by the Orange County, California, Environmental Health Division concerning a child with elevated blood lead levels. The child had consumed Storck brand Eucalyptus Menthol Candy.

A sample of the Storck candy was collected and analyzed by SAN-

DO. The wrapper was found to leach 33,000 ppm lead and the candy was found to contain 0.880 ppm lead. There is evidence that ink from the wrapper is the source of the lead and the amount of lead in the candy was shown to be related to the amount of pigmented ink that transferred to the candy.

The Storck candy was manufactured by Storck Products, Inc., Philippines under license of August Storck KG, 100 Berlin 27, F.R. Germany.

GUIDANCE: Districts may detain without physical sampling and analysis, all products identified on the attachment to this alert.

For the individually wrapped candies, both the candy and wrapper should be analyzed for lead in order to overcome the appearance of a violation. Additionally, adequate documentation should be provided showing that the manufacturer has addressed the problem and that the packaging materials (i.e., wrappers including inks) that may contact the food comply with the agency's requirements for contact materials.

In order to consider regulatory action, one of the following conditions must be met:

Analysis of the candy shows potentially harmful levels of lead:

Greater than 0.5 ppm lead, or 0.5 ppm or less lead, and a serving size that would result in a lead intake of 10 micrograms or more per serving. To calculate the amount of lead per serving in micrograms, multiply the lead level in the candy expressed as ppm, by the serving size of the candy expressed in grams. For example, if the lead level in the candy is 0.3 ppm and the serving size is 37 g. 0.3 x 37 = 11.1 micrograms per serving.

Evidence exists that lead has migrated from the wrapper/container to the Candy.

In some cases, there are visual indications of components of the wrapper (ink) migrating to the candy. SAN-DO has documented cases where the lead level is higher in the portion of the candy with a visual indication of migration.

Wrappers should be analyzed using a 24 hour leach at room temperature in a 1N HCL solution. Recommended lead methods of analysis are listed in Compliance Program 7304.019.

Districts should consider that each candy may present a different situation with regard to the potential for regulatory action. For example, the following considerations may be relevant:

is there both an inner and outer wrapper? If there is an inner wrapper, does it act as a barrier to lead migration?

is there ink on any surface that may come in contact with the candy? Is the ink on the inner or outer surface of the wrapper?

The Quick Color Test may be helpful as an indication of whether a packaging surface contains lead. Districts should contact CFSAN/DOE/Imports Branch, Doriliz Mestey, at (301) 436-2772 for questions concerning compliance or criteria for the release of lots.

For questions on issues concerning science, science policy, sample collection, analysis, preparation, or analytical methodology, contact the Division of Field Science, at (301) 827-7605.

PRIORITIZATION
GUIDANCE : I

FOI : No purging required.

KEYWORDS : Lead, Candy, Lollipop, Powder Candy, Storck eucalyptus-menthol candy.

PREPARED BY : Stella Notzon, DIOP (301) 443-6553

DATE LOADED
INTO FIARS : June 22, 2005

ATTACHMENT TO IMPORT ALERT #33-10 - 3/10/08

FIRM	PRODUCT/ PRODUCT CODE	MANUFACTURER/ SHIPPER	
MEXICO			
Candy Pop S.A. De C.V. Calle 26 No. 1815 Z. Industrial	Tamarind candy/lollipops 33S[][]06		M

Guadalajara, Jalisco, Mexico FEI# 3002809020	8/27/03		
Carmen Patricia Guzman Armenta Av. Plan de Iguala 1339 Col. Lazaro Cardenas Mexicali, Baja California, Mexico FEI #1000256653 MID #MXCARPAT1339MEX	Lollipop (Sucker) 33C[][]99/33S[][]06 11/8/94	M	
Fabrica de Dulces Ravi, S.A. de C.V. Bustamante #801 Colonia Los Nogales Monterrey, Nuevo Leon Mexico 64260 FEI #1000439056	Pancho's Hot Orange Jellies 33L--07	Manufacturer	
Industria Dulcera S.A. de C.V. Ave Miguel Hidalgo No 13 Morelia, Michoacan Mexico FEI #3000214092	Chaca Candy 33J[][]99 33S[][]99 33L[][]05 04/8 /04	M	
Margarita Guiltron Ramirez Guadalajara, Jalisco, Mexico FEI #1000333180 MID #MXMARRAM2GUA	Tamarind candy in ceramic jars Av. Rio Nilo #2038 Col Lomas	M	33Y[][]99 6/5/95
Productos Avila Sa De Cv, Puerto Melaque 1379 Col Sta Maria, Guadalajara, JAL, Mexico FEI # 3003809190	Chewing Gum in plastic baby bottles 33U[][]02 3/10/08	Manufacturer	

Productos Indy, S.A. De C.V., Ave. 25 De Mayo 158, Bodega A, Col, Fama, Santa Catarina, Nuevo Leon, Mexico FEI #3000218983	Hormigas Watermelon flavor Candy 33L[][]02 33E[][]06 33Y[][]99 33S[][]06 33C[][]99 33S[][]99 11/19/07	M

PHILIPPINES

Storck Products, Inc. West Capitol Drive Pasig, Metro Manila Philippines FEI #1000469384 MID #PHSTOPROMAN	Eucalyptus-Menthol Candy 33E[][]06 8/21/96	M

The firms below are reported to be shippers for this product:

CPMulti-Commodities Corporation

S

17 Clemente St., Bgy. San Agustin
Novaliches, Metro Manila
Philippines
FEI: 146
MID: PHCPMCOM17MET

Pacific Isles International Trading, Inc. S
62-9th Street, New Manila
Quezon City, Philippines
EFEI: #1000168008
MID: PHPACISL62QU

Productos Karla SA de CV Carretera Guadalajara-Saltillo, Km 187 Zacatecas, Tabasco, Mexico FEI # 1000475421	Vasito Tamarind & Guava flavored Soft Candy 33L[][]99, 33L[][]06, 33Y[][]99, 33S[][]99 11/1/06	M